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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,259	01/26/2004	Xiao-Chun (Chris) Le	033110-004	6473

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BUCHANAN INGERSOLL PC
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POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,259	LE, XIAO-CHUN (CHRIS)	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/2/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,11,12,16 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 11-12, 16 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-4, 11-12, 16 and 24 are pending and under examination.

In view of applicants' arguments the restriction/election requirement has been withdrawn. All of the pending claims would be examined.

Information Disclosure Statement

The listing of references in the specification (pages 1-4) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112, first paragraph

Claims 1-4, 11-12 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not contain an adequate written description for the claimed method for the group of factors as a chemical compound library, specifically a combinatorial chemical compound library. The specification contains only a generalized statement. It does not specify the different kind of components comprised in a library. Neither does the number or size or other characterizing features of a compound is contained therein. There is no description of how the combinatorial library is obtained. The manner by which the different components in a library can be labeled, the label used, the separation used to separate the different free compounds and/or bound complex in a library. There is not a single example that relates to a library. The description in all the working examples relate only to a single compound/complex, not a library. The specification recites that the invention resides in the combination of capillary electrophoresis(CE) and light induced fluorescence.

Claim 1 does not recite this limitation. The claim and/or specification do not contain any other means of separation except for CE.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 11-12 and 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the step by which the bound and free probes are separated into different fractions. The metes and bounds of a "group" of factors are unclear, especially in the absence of positive support in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 11-12, 16 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Laing et al (USP 6,331,392).

Laing discloses in e.g., the abstract a method screening for bioactive compounds, in particular those that bind to RNA sequences by assessing the stability and/or the conformation of an RNA target in the presence and absence of test ligands, and identifying as a ligand any test ligand that causes a measurable change in target RNA stability and/or conformation. The effect of a ligand on target RNA stability and/or conformation is assessed by measuring the fluorescence polarization of a fluorescently labeled probe. Probes include molecules which comprise fluorescent moieties whose measurable fluoresence properties, particularly polarization are sensitive to the stability and/or conformation of the target RNA as reflected in the binding state of the probe. "Probe" is any molecule to which

a fluorescent moiety is attached, in which one or more fluorescence properties are sensitive to the stability and/or conformation of the target RNA and/or to the binding state of the probe. Suitable probe compounds include without limitation nucleic acids, particularly oligonucleotides; small RNA-binding molecules exemplified by 2-deoxystreptamine antibiotics, which bind the Rev-responsive element in HIV RNA, or other compounds that specifically recognize the major or minor groove of RNA; and proteins, and peptides derived therefrom, that recognize particular RNA sequences or conformations. See Fig. 1. Test ligands may be derived from large libraries of synthetic or natural compounds. For example, synthetic compound libraries are commercially available. A chemical library is available from Aldrich (Milwaukee, Wis.). See the specifics of the method in Example 1. Accordingly, the specific process of Laing fully meets the broad claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at

> the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 11-12, 16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laing in view of Rothschild (USP 6,303,337).

Laing is discussed above. Laing does not disclose the use of capillary electrophoresis as recited in claim 2. However, Rothschild discloses at col. 41, line 64 up to col. 42, line 30 that capillary electrophoresis, has been found to be highly sensitive to interaction of proteins with other molecules including small ligands as long as the binding produces a change in the charge-to-mass ratio of the protein after the binding event. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use capillary electrophoresis separation in the method of Laing for the benefits derived therein as taught by Rothschild. This benefit would provide the modification to one having ordinary skill in the art to arrive at the claimed method.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 11, 15-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of U.S. Patent No. 6,132,968('968 Patent) in view of 6,331,392 ('392 Patent).

The claims and specification of the '968 Patent claims/discloses a method for quantitating at least one

modification of interest in a nucleic acid sequence contained in a sample, comprising: a) providing: i) a sample suspected of containing a nucleic acid sequence comprising the at least one modification of interest; ii) a first polypeptide sequence capable of specifically binding to the at least one modification of interest, and iii) a fluorescently labeled second polypeptide sequence capable of

specifically binding to the first polypeptide sequence (step a, as claimed); b) combining the sample, the first polypeptide sequence and the fluorescently labeled second polypeptide sequence to produce a fluorescently labeled second polypeptide sequence:first polypeptide sequence:nucleic acid sequence complex, (step b, as claimed) and a fluorescently labeled second polypeptide sequence:first polypeptide sequence complex; c) separating the fluorescently labeled second polypeptide sequence:first polypeptide sequence:nucleic acid sequence complex, the fluorescently labeled second polypeptide sequence:first polypeptide sequence complex and the fluorescently labeled second polypeptide sequence by capillary electrophoresis; d) detecting the separated fluorescently labeled second polypeptide sequence:first polypeptide sequence:nucleic acid sequence complex by laser-induced fluorescence; and e) quantitating the separated second

polypeptide sequence:first polypeptide sequence:nucleic acid sequence complex, thereby quantitating the at least one modification of interest in the nucleic acid sequence. Example 1, col. 20 up to Example 6, col. 27 provides detail steps of the method and the specific probes and polypeptides used in the method. The '968 Patent does not disclose fluorescence polarization. However, the '392 patent discloses the alternativeness of fluorescence and fluorescence polarization. It further discloses that particularly polarization are sensitive to the stability and/or conformation of the target RNA as reflected in the binding state of the probe. Accordingly, one would have been motivated to use fluorescence polarization in the method of the '968 Patent for the benefits derived therein as taught by the '392 Patent.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
June 23, 2006